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PRINCIPAL INVESTIGATOR: Karen M. Freund, M.D.

CONTRACTING ORGANIZATION: Boston Medical Center
Boston, Massachusetts 02118

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The usefulness of mammography to screen for breast cancer in women over 70 years of age is unknown, despite the fact that approximately 43% of all breast cancers occur in this age group. No previous randomized controlled trial (RCT) addressed women in this age group. Current guidelines on screening are therefore conflicting. Without clear evidence, the usefulness of the mammograms currently performed on 15-36% of women over age 70 is unknown.

Current mammography practice patterns and the costs associated with RCTs make it unlikely that a RCT will be conducted in women over age 70. Therefore, alternative data sources must be used to address this critical question. We present the use of an administrative utilization database linked to breast cancer outcomes to examine the usefulness of mammography in women age 70 and older. We will use the Linked Medicare-SEER Tumor Registry Database, created by the National Cancer Institute and the Health Care Financing Administration, that contains data on 10,611 women diagnosed with breast cancer from January 1, 1987 to December 31, 1993 to describe prior mammography utilization, stage at diagnosis and survival among women age 67-69, 70-74, 75-84, and 85+.

We have completed the creation of the analytic file, and examined prior mammography use. We have also described stage at analysis using Historical Staging System, and done initial analyses to relate mammography use to stage at diagnosis and survival.

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Karen Dunn June 8/98

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5.0 INTRODUCTION

Breast cancer is the second leading cause of cancer-related mortality among women in the United States. Women 65 years of age and older bear the greatest burden of disease accounting for more than 43% of newly diagnosed cases of breast cancer.[i] Older women are also more commonly diagnosed with advanced stage disease[1,2,3,4] and their breast cancer mortality rate is eight times greater than women under age 65.[5] The role of screening mammography in reducing morbidity and mortality from breast cancer in older women is unknown. Recent randomized controlled trials (RCTs) are inadequate to judge the efficacy of mammography screening, as they did not include sufficient women over age 69 years.

Current mammography practice patterns and the costs associated with RCTs make it unlikely that a RCT will be conducted in women over age 70. Therefore, alternative data sources must be used to address this critical question.

We present our methodology to data and data of a retrospective cohort study of 10,611 women age 67 and older with breast cancer, diagnosed from 1987 to 1993, in three geographic areas to estimate benefits from prior mammography use for women aged 67-69, 70-74, 75-84, and 85+ using the Linked Medicare-Tumor Registry Database. We have met the following technical objectives:

1) We have described prior mammography utilization.

2) We have begun to describe stage at breast cancer diagnosis, using the Historical Staging System.

3) We have begun to relate prior mammography use to stage at diagnosis using the Historical Staging System

4) We have begun to relate prior mammography use to survival.

5) For women age 67-79, we will compare results obtained in objectives 3 and 4 with those from RCTs to understand the magnitude of differences and the nature of adjustments necessary when estimating benefits from administrative data.

This study provides the first large scale population-based evidence of the utility of mammography screening for breast cancer in women over age 70. These findings provide the first data upon which to develop evidence-based guidelines on the use of screening mammography in women age 70 and older.

5.1 Background

Mammography Use in Older Women

Early detection with mammography has been consistently shown to decrease breast cancer-related mortality by 30% for women age 50-69 years.[6,7,8,9,10] Despite this striking reduction in mortality for women age 50-69, there are currently no data to make a statement about the utility of mammography for women age 70 and older. Although one RCT (The Swedish Two County Trial) included women up to age 74 years, there was inadequate power to detect a difference over age 69 years.

There are reasons to expect that older women would benefit from regular mammography despite the lack of scientific data to establish a benefit. First, mammography is a more specific and sensitive test as women age.[ii,11,12] Second, the biology of breast cancer in older women is thought to be similar to women age 50-69 years.[iii,iv,v,13] Third, survival times for older women are sufficiently long to benefit from early detection.[vi,14,15] Fourth, the cost effectiveness ratio of breast cancer prevention in the elderly is in a reasonable range.[16,17]

Given the lack of scientific data on the usefulness of mammography in women age 70 and older, current practice recommendations vary. Annual mammography is recommended by the American Cancer Society[13] and the American Medical Association Council on Scientific Affairs[18] for women after age 50 with no upper age limit. Annual to biennial mammography is recommended for women age 50-74 by the U.S. Preventive Services Task Force.[19] The Task Force does not recommend mammography beyond age 74.[19] Annual mammography is recommended for women age 65-74 by the Forum on Breast Cancer Screening in Older Women. The Forum also suggests that mammography "should be encouraged" at regular intervals of approximately every two years for women age 75 and older whose general health and life expectancy are good.[20]

Breast Cancer Survival in Older Women

There are several potential explanations for why older women experience poor breast cancer survival. These include suboptimal use of breast cancer screening, advanced stage at diagnosis, less aggressive workup, and more conservative therapy.

A series of national surveys (Behavioral Risk Factor Surveillance System, Mammography Attitudes and Usage Study, National Health Interview Survey) have documented that mammography use decreases with advancing age.[11,21,22] In 1993, only 25% of women age 65 and older on Medicare had at least one mammogram.[23] Rates of mammography utilization among women age 65-74, 75-84 and 85+ years were 32%, 21%, and 7%, respectively.[23] Factors other than age that influence mammography use in older women include race, income, education, and state of residence.[24,25] However, having a regular provider is the most important determinant of mammography use.[26,27,28] We examined mammography utilization among women age 65 and older and found that these sociodemographic factors remained independent predictors of mammography use even after accounting for use of primary care.[29]

The stage of breast cancer at diagnosis is the most important predictor of prognosis. Women who are diagnosed while their cancer is localized to the breast experience better 5-year relative survival rate as compared with women diagnosed with more advanced disease (90% versus 64%, respectively).[13] Older women are more likely to be present with advanced disease and are more likely to go unstaged as compared with younger women disease.[13,23] Furthermore, age is an independent predictor of advanced stage disease even after adjusting for other important factors (race, marital status, income, education, and source of care).[30,31,32,33,34]

Age has been shown to influence the diagnostic evaluation and treatment offered for breast cancer.[35,36,37,38] Older women are less likely to receive diagnostic valuations as complete or treatment as aggressive as compared with younger women. However, the poor survival experienced by the older women can primarily be attributed to their advanced stage at diagnosis since stage-specific survival is similar in all age groups and age-related treatment differences do not appear to affect survival.[39]

6.0 BODY

6.1 Methods

6.11 Data Source:

We conducted a retrospective cohort study using the Linked Medicare-Tumor Registry Database. [40] The linked database was jointly created by the National Cancer Institute (NCI) and the Health Care Financing Administration (HCFA) to enable researchers to conduct cancer-related health services research. The linked database contains cancer information on patients aged 65 years and older from NCI's SEER Program linked with Medicare enrollment and utilization information from HCFA's Medicare Statistical System for the years 1985 to 1994.

We requested the SEER-Medicare Linked Database from the National Cancer Institute immediately after we were notified that our study was funded by the Department of Defense Breast Cancer Research Program. Within approximately six weeks, we received forty-two 3280 cartridges containing Medicare information on women diagnesed with breast cancer in the SEER Program and the SEER Public Use file on compact disk. These cartridges were sequentially uploaded to a UNIX machine to begin constructing the analytic file from several data sources. We combined information from the SEER Patient Entitlement and Diagnosis Summary File with Medicare denominator files for the years, 1985 to 1994, to identify patients eligible for out study sample. Once we defined our study sample, we identified all Medicare claims from two utilization files available in the linked database. Medical Provider Analysis and Review (MEDPAR) is a 100 percent utilization file with one record for every inpatient hospitalization or skilled nursing facility stay covered under Medicare Part A. The Physicians' Claims file is a 100 percent utilization file with one record for every physician and outpatient claim covered under Medicare Part B. Prior to 1991, the Physicians' Claims file was only available for ten states. Data from the SEER and Medicare Programs overlap in three tumor registries: Connecticut, metropolitan Atlanta, Georgia, and Seattle-Puget Sound, Washington. Specific information describing the linkage between SEER and Medicare has been published elsewhere.[40] The match rates for Connecticut, Atlanta, and Seattle are 93.3%, 94.1%, and 91.5%, respectively.

6.12 Study Sample:

Women were eligible for the study sample (n=11,399) if they were diagnosed with a first primary breast cancer between January 1, 1987 and December 31, 1993, aged 67 years and older, and resided in Connecticut, Atlanta, or Seattle-Puget Sound. Although we selected these areas because physicians' claims were available for all cases, they represent a geographically diverse population of older women with breast cancer. Women who were enrolled in a health maintenance organization (HMO) and those with less than two full years of Medicare Part B coverage were not eligible for this study, since physician claims data, which are required for identifying mammography use, are not available. We limited our final study sample to women who were aged 67 years and older to ensure that all women had a minimum of two years of Medicare utilization (claims) information prior to their breast cancer diagnosis.

Women whose mammography use could not be categorized (n=788) were excluded from the study. The final study sample consisted of 10,611 women.

6.13 Measures:

We ascertained the following sociodemographic variables from the SEER file: age at diagnosis, marital status at diagnosis, and SEER area. Age at diagnosis (range 67-107 years) was categorized as 67-74, 75-84, and 85 and older for descriptive purposes, but was modeled as a continuous variable (only four women were over 100 years of age). Marital status was defined as married or not at diagnosis. SEER area was classified according to the tumor registry of diagnosis: Connecticut, Atlanta, or Seattle. We used 1990 U.S. Census data as an ecological measure of socioeconomic status (SES). Women were assigned to the median household income of their zip code of residence and grouped as < $25,000 or ≥ $25,000.

We obtained information on race from the Medicare beneficiary enrollment file. A comparison of race between Medicare and SEER files demonstrated agreement for 99% of women. Enrollees are classified in Medicare files as Black, White, Asian, Native American, Hispanic, or unspecified.

We computed a modified Charlson Comorbidity Index using Deyo's method of classifying ICD-9-CM diagnosis codes from inpatient claims.[41] For each woman, we identified all inpatient hospitalizations beginning two years prior to diagnosis and ending one month after diagnosis. A priori, we extended the period of observation to one month past diagnosis because we expected that, during the study years 1987 to 1993, most women would have had at least one hospitalization around their breast cancer diagnosis. We classified women as 1) non-hospitalized (i.e., comorbidity could not be assessed), 2) no comorbid conditions (i.e., a Charlson Index of 0), and 3) one or more comorbid conditions (a Charlson Index of 1 or greater).

We measured mammography utilization using Medicare physicians' claims. We identified women who had one or more bilateral mammograms (CPT procedure codes 76091 or 76092) within two years prior to their breast cancer diagnosis. We classified women as: 1) *nonusers* (n=2,320) if they did not have any mammograms during the entire two year period prior to their diagnosis, 2) *regular users* (n=2,560) if they had at least two mammograms within the two years prior to their breast cancer diagnosis that were ten or more months apart, and 3) *peri-diagnosis users* (n=5,731) if they had their only mammogram(s) within three months before their diagnosis. Women who did not fit into any category listed above were classified as *Uncertain* (n=768) and excluded from the study. "Peri-diagnosis users" were a heterogeneous group of women whose only mammography use was close to their date of diagnosis. This group includes women who had a screening mammogram and were diagnosed with breast cancer and those who had a diagnostic mammogram. Therefore, analyses relating prior mammography use to stage at diagnosis considered only nonusers and regular users, as they are two distinct groups of women.

We will be able to measure stage at diagnosis using two staging systems: the historical staging system and the SEER modified TNM staging system of the American Joint Commission on Cancer. For our initial analysis, we measured stage at diagnosis using the historical staging system (in situ, localized, regional, distant or unstaged) because it was available for all women. We categorized stage of disease as early (in situ/localized) or late (regional/distant). We also will carefully examine women with unstaged disease. We plan to repeat all our analyses using the TNM stets to determine if our results vary.

6.2 RESULTS

6.21 Characteristics of the Study Sample:

Our study sample consists of 10,611 women aged 67 and older. Forty-six percent of the women (n=4,934) were aged 67 to 74 years at the time of their breast cancer diagnosis, 42% (n=4,408) were aged 75 to 84 years, and 12% (n=1,269) were aged 85 years or older. Overall, 93% of the women were white, 4% were black, and 3% were of other racial backgrounds. Forty-eight percent resided in Connecticut, 35% resided in Seattle, and 17% in Atlanta. Thirty-eight percent of the women were married, and 9% resided in a low-income area (i.e., a zip code area with a median income of less than $25,000). Approximately, one-quarter of the women were not hospitalized, 52% of the women had no identified comorbidities, and 22% of the women had at least one comorbid condition.

6.22 Mammography Use:

Twenty-two percent of the women had no mammograms within two years prior to their breast cancer diagnosis (nonusers), 24% of women had at least two mammograms within two years preceding diagnosis that were ten or more months apart (regular users), and 54% of the women had their only mammogram(s) within three months prior to their diagnosis (peri-diagnosis users). Regular mammography use decreased with advancing age at diagnosis; 29% of women aged 67-74 years, 23%of women aged 75-84 years, and 9% of women age 85 years and older.

6.23 Stage at Diagnosis:

Using the historical staging system, we also found that one-third (32%) of the women were diagnosed with regional or distant disease and 3% were unstaged and that women of the oldest age group (age $\geq$ 85 years) were more likely to be diagnosed with advanced stages of breast cancer and to be unstaged as compared to women of the two younger age groups. Advanced breast cancer was diagnosed in 28%, 28%, and 32% of women aged 67-74, 75-84, and $\geq$ 85 years, respectively. Ten percent of women $\geq$ 85 years were unstaged as compared to 2% of women 67-74 years and 3% of women 75-84 years.

6.24 Relationship Between Mammography Use and Stage at Diagnosis:

We preformed preliminary analyses to relate mammography use to stage at diagnosis for all women and women within each age group. In our initial analyses, we used the historical staging system to classify women as early (in situ/local) and late (regional/distant). The unadjusted and adjusted odd ratios for late stage disease comparing nonusers with regular users (n = 4,880) are shown in Table 1. We found that mammography use was important for all women and women in each age group. We also found that even after adjusting for factors that have been found to be associated with late-stage disease at diagnosis, including age at diagnosis, race, marital status, income of zip code of residence, and comorbid conditions, lack of mammography use remained a significant predictor of late-stage at diagnosis in all women (aOR=2.9, 95% CI 2.5-3.3) within each age group: age 67-74 (aOR=2.3, 95% CI 1.9-2.8); 75-84 (aOR=3.7, 95% CI 3.0-4.6); and $\geq$ 85 years (aOR=4.1, 95% CI 2.2-7.4).

Since women age 85 years and older are more apt to go unstaged and prior research has shown that unstaged women have poorer breast cancer survival, we repeated our preliminary analyses to include the unstaged women and classify them as having late staged disease. As shown in Table 2 the importance of mammography use remains for women of all age groups.

6.25 Relationship Between Mammography Use and Survival:

We have recently started to examine the relationship between mammography use and survival. In the initial data tapes received from SEER, we do not have information on whether or not a woman died from her breast cancer, therefore we conducted preliminary analyses to examine the relationship between mammography use and all-cause mortality. Breast cancer-related mortality will be our ultimate survival outcome since we hypothesize that mammography use should have an impact on breast cancer related deaths. All-cause mortality tends to bias the relative risk of mortality towards 1.00 making it more difficult to detect any differences. In fact, we are able to demonstrate an association between all-cause mortality and mammography use. Table 3 demonstrates that nonusers were at significantly greater risk of death than regular users (aRR=2.6 95% CI 2.2-3.0) and had greater risk of dying within each age group: age 67-74 (aRR=2.6, 95% CI 2.0-3.3); 75-84 (aRR=2.6, 95% CI 2.1-3.3); and $\geq$ 85 years (aRR=2.3, 95% CI 1.6-3.5). We have subsequently received data on breast-cancer specific mortality and will be able to relate mammography use to disease specific mortality.

Table 1. Unadjusted and Adjusted Odd Ratios for Late Stage Disease Nonusers Compared with Regular Users (n = 4,667)

Historical Staging System (unstaged are excluded n=213)
(In situ/local vs. Regional/distant)

	Late Stage at Diagnosis	
	Unadjusted OR (95% CI)	**Adjusted* OR (95% CI)**
All Women (n=4667)	3.0 (2.6-3.4)	2.9 (2.5-3.3)
Age 67 to 74 (n=2288)	2.3 (1.9-2.8)	2.3 (1.9-2.8)
Age 75 to 84 (n=1890)	3.8 (3.1-4.7)	3.7 (3.0-4.6)
Age ≥ 85 (n=489)	4.4 (2.5-7.7)	4.1 (2.3-7.4)

*Adjusted for age at diagnosis, race, marital status, income of ZIP Code, and comorbidity.

Table 2. Unadjusted and Adjusted Odd Ratios for Late Stage Disease Nonusers Compared with Regular Users (n = 4,880)

Historical Staging System (unstaged are included as late)
(In situ/local vs. Regional/distant/unstaged)

	Late Stage at Diagnosis	
	Unadjusted OR (95% CI)	**Adjusted* OR (95% CI)**
All Women (n=4880)	3.3 (2.9-3.8)	3.3 (2.7-3.5)
Age 67 to 74 (n=2335)	2.3 (1.9-2.8)	2.3 (1.9-2.8)
Age 75 to 84 (n=1964)	4.1 (3.4-5.1)	3.9 (3.4-4.8)
Age ≥ 85 (n=581)	5.5 (3.3-9.2)	5.2 (3.0-8.9)

*Adjusted for age at diagnosis, race, marital status, income of ZIP Code, and comorbidity.

Table 3. Unadjusted and Adjusted Relative Risk of Mortality by Age at Diagnosis
Nonusers Compared with Regular Users (n =4,400)

	All Cause Mortality	
	Unadjusted RR (95% CI)	**Adjusted* RR (95% CI)**
All Women (n=4400)	3.4 (3.1-3.9)	2.6 (2.2-3.0)
Age 67 to 74 (n=2037)	2.9 (2.3-3.6)	2.6 (2.0-3.3)
Age 75 to 84 (n=1802)	2.7 (2.2-3.3)	2.6 (2.1-3.3)
Age ≥ 85 (n=563)	2.7 (1.8-3.9)	2.3 (1.6-3.5)

*Adjusted for age at diagnosis, race, marital status, income of ZIP Code, comorbidity, and year of diagnosis.

HProportional Hazards models were stratified on SEER area.

6.3 DISCUSSION

Our preliminary results show a striking association between prior regular mammography use and two outcomes 1) early stage of disease, using the historical staging system, and 2) all cause mortality. These data are based on a cohort of over 10,000 women with breast cancer over seven years in three geographic regions of the United States. Data collection on breast cancer diagnosis, stage, and mortality is collected prospectively, and therefore does not have the risk of recall bias. Controlling for potential confounders of the findings including age, race, income, comorbidities and marital status did not influence the results. The findings of earlier stage disease and decreased mortality in the screening group persist across all age groups, including the oldest old. This is the first data to suggest a continued benefit of screening mammography beyond age 70.

These results are based on administrative claims data and not randomized control trial data, and are limited to the potential biases of such data. Lead time bias may explain some of these findings. Our planned comparison of our findings with the randomized controlled trials in objective number #5 will allow us to quantify the effect of potential lead time bias. A healthy cohort effect of women who receive screening is also possible, and may not be completely captured by our comorbidity measure.

We plan to submit the findings of the stage analysis as the first manuscript of this project this summer. This data will be presented at the SEER-Medicare Data Users Workshop on June 24,1998 at the National Institute of Health, National Cancer Institute.

6.4 STATEMENT OF WORK

We have met all the objectives of our statement of work for the first 12 months of the project. We have also done preliminary analyses for tasks in objectives 2, 3 and 4, which are scheduled under the original statement of work to be completed in year 2 of the project.

Technical Objective 1: Describe prior mammography utilization

Task 1: Analytic file completed and database organized.
Task 2: Explanatory variables created, and frequencies examined.
Task 3: Prior mammography measure finalized.
Task 4: Mammography use described for each age group.

Technical Objective 2: Describe stage at breast cancer diagnosis.

Task 1: Have created outcome variable for historic staging, examining unstaged cases. TNM staging variable created but not analyzed.
Task 2: Have examined documentation of stage evaluation.
Task 5: To be completed month 17 – 18. Have completed preliminary analysis for historical staging system.

Technical Objective 3: Relate mammography utilization to stage

Task 1: To be completed Month 19-22. Have completed preliminary analysis of the historical stageing system.

Technical Objective 4: Relate mammography utilization to survival.

Task 1: Constructed all cause mortality measure.
Task 2: Conducted analysis of prior mammography us to all cause mortality.

7.0 CONCLUSIONS

The work of our project is proceeding on schedule, with database development complete, and analyses underway. We anticipate completing the project on schedule.

Our preliminary findings show a striking continued benefit of mammography use after age 65, without evidence of an age cutoff for the benefit. Further work is required to address as best as possible alternate explanations of the findings and biases, including lead time bias. This data is the first to suggest that we should continue to recommend the use of screening mammography women over the age of 70 years.

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